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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:

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Premanufacture Notice Number:

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P-15-502

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Consent Order and Determinations Supporting Consent Order

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PREAMBLE

I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act (“TSCA”) (15 U.S.C. 2604(e)), the Environmental Protection Agency (“EPA” or “the Agency”) issues the attached Order, regarding premanufacture notice (“PMN”) P-15-502 for the chemical substance

_____ (“the PMN substance”) submitted by _____ (“the Company”), to take effect upon expiration of the PMN review period. The Company submitted the PMN to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for this PMN substance requires the Company to:

- (a) submit to EPA certain fate testing before manufacturing (defined by statute to include import) a total of _____ of the PMN substance;
- (b) not use the PMN substance in consumer spray products; and
- (c) maintain certain records.

III. CONTENTS OF PMN

By signing this Order, the Company represents that it has carefully reviewed this document and agrees that all information herein that is claimed as confidential by the Company is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

Confidential Business Information Claims (Bracketed in the Preamble and Order):

Company, chemical identity, use, production volume, test data

Chemical Identity:

Specific:

Generic: Perfluorobutanesulfonamide and polyoxyalkylene containing polyurethane

Use:

Specific: [

Generic: protective treatment

Maximum 12-Month Production Volume:

Test Data Submitted with PMN: analog health toxicity, analog aquatic toxicity, and analog fate

IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK

The following are EPA's predictions regarding the probable human and environmental toxicity, human exposure and environmental release of the PMN substance, based on the information currently available to the Agency.

Human Health Effects Summary: EPA has concerns for potential incineration products or other

decomposition products of the PMN substance. EPA also has concerns that under some conditions of use, particularly non-industrial, commercial, or consumer use, the PMN substance could cause lung effects, based on limited data on some perfluorinated compounds. Concerns for the PMN substance are for lung toxicity from waterproofing of lung membranes, based on PMN properties. Concerns for the potential ultimate perfluorinated degradation products are for liver toxicity, blood toxicity (anemia), kidney toxicity, and developmental toxicity at high doses, based on [] Carcinogenicity of [] has not been tested in animals.

EPA has concerns for the potential degradation intermediates and products, byproducts, unreacted material and low molecular weight species. The PMN substance is a derivative of [] and may degrade to form [] and not further degrade. [] is persistent and mobile in the environment.

Concerns for the PMN substance are based on data on an analog, [] and data on [] and analogy of [] to perfluorooctane sulfonate (PFOS). [] was tested in a rat reproductive/developmental screen via the oral route of exposure at doses of 50, 150, and 1000 mg/kg/day with a no observed effect level (NOEL) of 150 mg/kg/day. Reproductive and developmental effects were observed at 1000 mg/kg/day.

Thermal degradation analysis on some structurally similar substances demonstrates that the perfluoro component of the PMN substance may be released to the environment from incomplete incineration at low temperatures. Also, preliminary evidence suggests that, under some conditions, the PMN substance could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate, and could be toxic

(PBT) to people, wild mammals, and birds based on data on the analog chemical, PFOS and other analogous perfluoroalkyl sulfonates (PFAS).

PFOS is expected to persist for years in the environment. Biodegradation and photolysis tests of analogous substances indicate little or no biodegradation or photolysis of perfluoroalkyl compounds. Bioaccumulation concerns are based on concerns raised by the measured presence of certain perfluoroalkyl compounds with longer carbon chain lengths, including PFOS, in wildlife and in human blood samples. Toxicity studies on PFOS indicate developmental, reproductive and systemic toxicity in various species. These factors, taken together, raise concerns for potential adverse chronic effects in humans and wildlife. For information about PFOS, see *Hazard Assessment and Biomonitoring Data on Perfluorooctane Sulfonate (PFOS)* found in docket, OPPT-2002-0043-0010. Additional information about PFOS may also be found in the *Administrative Record for PFOS, PFOA, and Telomers and Related Chemicals (AR-226)*. *Administrative Record (AR-226)* is not currently available online, but copies can be requested on CD-ROM from the EPA Docket office by calling (202) 566-0280, or by sending an email request to ncic.oppt@epa.gov.

Toxicological, ecological, and fate data now exist on _____ and some of the _____]-derived polymers and other substances; see the PMN docket for _____ and related PMN dockets. A pharmacokinetics study on _____ in the Cynomolgus Monkey was submitted with a Prenotice Communication _____ for a PMN substance _____ and later finalized _____. This study indicates that the serum half-life of _____ in these monkeys is less than 24 hours. A subsequent epidemiological study shows that the half-life of _____ in humans is approximately one month, whereas the half-life of PFOS in monkeys is 200 days and in humans is approximately 5.4 years (OECD Hazard Assessment of Perfluorooctane

Sulfonate (PFOS) and its Salts, 2002, also found in OPPT-2002-0043-0023). These data and assessments support the assessment of reduced bioaccumulation of _____ relative to PFOS. EPA review of the subchronic and reproductive data on _____ show subchronic effects to the liver, blood (anemia), kidney, and developmental toxicity. Although these and other data indicate a different and less toxic toxicological and ecological profile for _____ in the test species in the data to date than for PFOS and PFOA, EPA believes that, based on the persistence of _____, potential intermediate fate products, and the fact that these products may be major substitutes for some uses of PFOS, more information is warranted on the fate and physical/chemical properties of _____ polymers in the environment. EPA also believes that long-term toxicological testing on PFBS may be warranted, based on these factors and uncertainty.

Environmental Effects Summary: EPA expects the PMN substance to be highly persistent.

No ecotoxicological concerns were raised for the intact PMN substance per se. No significant effects have been seen in the ecotoxicological laboratory data on _____, the potential ultimate fate product, to date. EPA has evaluated the avian reproduction study on _____ and found no significant effects. As stated previously, the analog, PFOS is persistent in the environment and has a long bioretention time in various species. It has been shown to bioconcentrate in fish. It has been detected in a number of species of wildlife, including marine mammals. It is toxic to mammalian and other species (OECD 2002). The presence in the environment and the toxicological properties of PFOS continue to be investigated.

Exposure and Environmental Release Summary: Thermal and simulated incineration testing exists on related polymers. This testing indicates that incomplete incineration products are formed at lower temperatures. Modified Zahn-Wellens and Semi-Continuous Activated Sludge ("SCAS") biodegradation tests have been conducted on some related polymers. EPA has determined that some related polymers degrade. EPA has received and reviewed test data showing that certain polymers with perfluoroalkyl substituents degrade to form perfluoroalkyl-containing intermediates and perfluoroalkyl-containing organic acids. EPA believes that further testing on P-15-502 is warranted to further elucidate the environmental fate of this substance.

Use of this substance is as a _____ No uses
are envisioned that would entail a spray application.

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

(a) EPA is unable to determine the potential for human health and environmental effects from exposure to the PMN substance and its potential intermediate and/or ultimate degradants. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substance.

(b) In light of the potential risk of human health and environmental effects posed by the uncontrolled manufacture (defined by statute to include import), processing, distribution in

commerce, use, and disposal of the PMN substance, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture (defined by statute to include import), processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health and the environment.

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Triggered Testing. The Order prohibits the Company from exceeding a specified production volume unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.

Pended Testing. The following additional information would be required to evaluate certain degradation potential of the PMN substance:

<u>Information</u>	<u>Guidelines</u>
Phototransformation of Chemicals on Soil Surfaces	OECD Draft Document Jan. 2002

The Order does not require submission of the above pended testing at any specified time or production volume. However, the Order's restrictions on manufacture (defined by statute to include import), distribution in commerce, and use of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the chemical substance

(P-15-502)("the PMN substance") in the United States by

] ("the Company"), except to the extent that those activities are exempted by paragraph

(b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substance is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Export. Until the Company begins commercial manufacture of the PMN substance for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substance solely for export in accordance with TSCA

§§12(a) and 12(b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substance for use in the United States, no further activity by the Company involving the PMN substance is exempt as “solely for export” even if some amount of the PMN substance is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substance while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substance that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(2) Research & Development (“R&D”). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance when manufactured solely for non-commercial research and development per TSCA §5(i) and 40 CFR 720.30(i).

(3) Byproducts. The requirements of this Order do not apply to the PMN substance when it is produced, without separate commercial intent, only as a “byproduct” as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substance when it is manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(5) Imported Articles. The requirements of this Order do not apply to the PMN substance when it is imported as part of an “article” as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(6) Completely Reacted (Cured). The requirements of this Order do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(c) Automatic Sunset. If the Company has obtained for the PMN substance a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

**II. TERMS OF MANUFACTURE (INCLUDING IMPORT), PROCESSING,
DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL
PENDING SUBMISSION AND EVALUATION
OF INFORMATION**

PROHIBITION

The Company is prohibited from manufacturing (defined by statute to include import), processing, distributing in commerce, using, or disposing of the PMN substance in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

TESTING

(a) Section 8(e) Reporting. Reports of information on the PMN substance which reasonably supports the conclusion that the PMN substance presents a substantial risk of injury to health or the

environment and which is required to be reported under TSCA section 8(e) shall reference the appropriate PMN identification number for this substance and contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found at www.epa.gov/oppt/tsc8e.

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Monitoring Assistance and Media Programs Division (2227A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

- (1) The date when the study is scheduled to commence;
- (2) The name and address of the laboratory which will conduct the study;
- (3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study; and,
- (4) The appropriate PMN identification number for each substance and a statement that the substance is subject to this Consent Order.

The written notice should be submitted to EPA as follows:

Postal Mail Address

U.S. Environmental Protection Agency

GLP Section Chief – Pesticides, Water and Toxics Branch

Monitoring Assistance and Media Programs Division (2227A)

Office of Enforcement and Compliance Assurance

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

Courier Delivery Address

U.S. Environmental Protection Agency

GLP Section Chief – Pesticides, Water and Toxics Branch

Monitoring Assistance and Media Programs Division (2227A)

Office of Enforcement and Compliance Assurance

Room 7117B

1200 Pennsylvania Avenue, N.W.

Washington, DC 20004

(c) Good Laboratory Practice Standards and Test Protocols. Each study performed to address the risks identified in this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any study that will use a modified version of a published test guideline, the Company must submit written test protocols to EPA for review (submission of written test protocols is optional for tests that are to be conducted using unmodified published test guidelines). Protocols must be submitted as a support document for the PMN, using the procedures set out in 40 CFR 720.40. EPA will respond to the Company within 4 weeks of receiving the written protocols. EPA review of a test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements. The Company is prohibited from manufacturing (defined by statute to include import) the PMN substance after an aggregate domestic manufacture and import volume of _____ (“the production limit”), unless the Company conducts an aerobic and anaerobic transformation in soil test (OECD TG 307) on the P-15-502 substance and submits all final reports and underlying data in accordance with the conditions specified in this Testing section.

If at any point the Company believes that sufficient data have been collected, they should consult with EPA prior to terminating the test. If the Company makes a decision to terminate the test before sufficient data has been collected the test data will be declared invalid.

Until the Company submits all final reports and underlying data, the Company shall submit annually to EPA a letter reporting the cumulative manufacture (which includes import) volume of the PMN substance for the previous calendar year following commencement of manufacture. This letter must be submitted as a support document for the PMN, using the procedures set out in 40 CFR 720.40.

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit the final report of each study (with an additional sanitized copy, if confidential business information is involved) and all underlying data (“the report and data”) to EPA prior to exceeding the applicable production limit. The final report and data must be submitted as a support document for the PMN, using the procedures set out in 40 CFR 720.40.

The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting," "Data and Reporting," and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will require the submission of raw data such as slides and laboratory notebooks only if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture (defined by statute to include import) the PMN substance beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e) (except that the study may be submitted after reaching the applicable production limit). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substance, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by

a study are scientifically invalid, the Company is prohibited from further manufacture (defined by statute to include import) of the PMN substance beyond the applicable production limit.

(2) The Company may continue to manufacture (defined by statute to include import) the PMN substance beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) If there is sufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may reconduct the study. If there is insufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may exceed the production limit, but must otherwise comply with paragraphs (b), (c), and (e), and shall submit the report and data to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) Company Determination of Invalid Data.

(1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c)

and (e), the Company remains prohibited from further manufacture (defined by statute to include import) of the PMN substance beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture (defined by statute to include import) the PMN substance beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e), if there is sufficient time to conduct or reconduct the study and submit the report and data to EPA before exceeding the production limit specified in paragraph (d). If there is insufficient time for the Company to comply with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may exceed the production limit, but must otherwise comply with paragraphs (b), (c), and (e), and shall submit the report and data to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture (defined by statute to include import) beyond the applicable production limit.

(j) Unreasonable Risk.

EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN

substance will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture (defined by statute to include import), processing, distribution, use and/or disposal of the PMN substance to mitigate exposures to or to better characterize the risks presented by the PMN substance. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture (defined by statute to include import), processing, distribution, use and disposal of the PMN substance, unless either:

(1) within 2 weeks from receipt of the EPA notice, the Company complies with such requirements as the notice specifies; or

(2) within 4 weeks from receipt of the EPA notice, the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture (defined by statute to include import), process, distribute, use and dispose of the PMN substance in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture (defined by statute to include import), processing, distribution, use and disposal of the PMN substance.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant

information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part VI. of this Consent Order.

RISK NOTIFICATION

(a) If as a result of the test data required under the terms of this Order, the Company becomes aware that the PMN substance may present a risk of injury to health or the environment (or is so notified by EPA), the Company must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet ("MSDS"), as described in 40 CFR section 721.72(c), within 90 days from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured (defined by statute to include import), processed, or used in the Company's workplace, the Company must add the new information to an MSDS before the PMN substance is reintroduced into the workplace.

(b) The Company must ensure that persons who will receive the PMN substance from the Company, or who have received the PMN substance from the Company within 5 years from the date the Company becomes aware of the new information described in paragraph (a) of this section, are provided an MSDS containing the information required under paragraph (a) within 90 days from the time the Company becomes aware of the new information.

MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture (defined by statute to include import) of the PMN substance by any other person.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture (defined by statute to include import) the PMN substance of the existence of the SNUR.

USE

(a) The Company shall not use the PMN substance for consumer spray application products.

DISTRIBUTION

(a) Export Notice Requirement. No later than the date of distribution, the Company shall notify in writing any person to whom it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(b) Distribution Requirements. Except after the PMN has been completely reacted (or cured), or as provided in paragraph (c), the Company shall distribute the PMN substance outside the Company, other than for disposal, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Notify in writing any person to whom it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(2) Not further distribute the PMN substance to any other person, other than for disposal, until after the PMN substance has been completely reacted (cured).

(3) Not use the PMN substance in consumer spray products.

(c) Test Marketing. The requirements of this Distribution section do not apply to distribution in commerce of the PMN substance in small quantities solely for test marketing as in accordance with 40 CFR 720.3(gg). Test marketing of the PMN substance as a component of a consumer product for spray application is prohibited.

(d) Temporary Transport and Storage. Notwithstanding paragraph (b), the Company may distribute the PMN substance outside the Company for temporary transport and storage in sealed containers provided the following three conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers, the

PMN substance may be distributed only to the Company or a person who has given the Company the written agreement required by paragraph (b).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substance may occur only while the PMN substance is in the possession and control of the Company or a person who has given the Company the written agreement required by paragraph (b).

(3) The Company shall ensure that each of the sealed containers of the substance leaving its workplace for distribution in commerce is labeled with the following information: A statement of the health hazards(s) and precautionary measure(s), if any, identified by the Company for the PMN substance; the identity by which the PMN substance may be commonly recognized; a statement of the environmental hazard(s) and precautionary measure(s), if any, identified by the Company for the PMN substance; a statement of exposure and precautionary measure(s), if any, identified by the Company for the PMN substance; and the name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures. The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(e) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substance, the Company obtains knowledge that a recipient of the substance has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section or, after subparagraph (b) expires in accordance with subparagraph (f)(1), has engaged in a significant new use of the PMN substance (as defined in 40 CFR Part 721, Subpart E) without submitting a

significant new use notice to EPA, the Company shall cease supplying the substance to that recipient, unless the Company is able to document each of the following:

(1) That the Company has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (b) of this Distribution section and will comply with those terms, or is aware of the terms of the significant new use rule for the PMN substance and will not engage in a significant new use without submitting a significant new use notice to EPA.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (e)(2) of this Distribution section, the Company obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA, the Company shall cease supplying the PMN substance to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substance to that recipient only upon written notification from the Agency.

(f) Sunset Following SNUR and Notification of SNUR. (1) Paragraphs (b) and (d) of this Distribution section shall expire 75 days after promulgation of a final SNUR for the PMN substance under section 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified,

subparagraph (b)(2) of this Distribution section shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) When EPA promulgates a final SNUR for the PMN substance and subparagraph (b) of this Distribution section expires in accordance with subparagraph (e)(1), the Company shall notify each person to whom it distributes the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the Federal Register or the Code of Federal Regulations.

III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substance did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substance eligible for the export only exemption in Section I, Paragraph (b)(1) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substance

eligible for the research and development exemption in Section I, Paragraph (b)(2) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substance claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture (defined by statute to include import) volume of the PMN substance and the corresponding dates of manufacture (defined by statute to include import);

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture (defined by statute to include import) to whom the Company directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(4) Records documenting the address of all sites of manufacture (defined by statute to include import), processing, and use;

(5) Records documenting compliance with any applicable manufacturing, use, and distribution restrictions in the Manufacturing, Use, and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;

(6) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and,

(7) The Company shall keep a copy of this Order at each of its sites where the PMN substance is manufactured (defined by statute to include import).

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget ("OMB"), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substance. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request include, but are not limited to, the following:

(1) Expected dates and times when the PMN substance will be in production within the subsequent 12 months;

(2) Current workshift schedules for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(3) Current job titles or categories for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(4) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(5) Records required by the Recordkeeping section of this Order; and/or,

(6) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response shall be in writing. To the extent the information is known to or reasonably ascertainable by the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN

substance, including the right to manufacture the PMN substance, to another person outside the Company (the “Successor in Interest”).

(b) Relation of Transfer Date to Notice of Commencement (“NOC”).

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import (“NOC”) for the PMN substance from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture (defined by statute to include import) of the PMN substance.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit a new PMN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) “Successor in Interest” means a person outside the Company who has acquired the Company’s full interest in the rights to manufacture the PMN substance, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substance. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3) and 40 CFR 720.3(z).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substance, including the right to manufacture the PMN substance, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment B to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to:

The written notice should be submitted to EPA as follows:

Postal Mail Address

U.S. Environmental Protection Agency
New Chemicals Management Branch (7405M)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Courier Delivery Address

U.S. Environmental Protection Agency
New Chemicals Management Branch (7405M)
1201 Constitution Avenue, N.W.
Washington, D.C. 20004

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substance is manufactured (defined by statute to include import). Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the PMN substance under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substance pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substance manufactured (defined by statute to include import) by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the human health or environmental effects of, or human exposure to or environmental release of, the PMN substance, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.


In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

(a) Waiver. By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

(b) CBI Brackets. By signing this Order, the Company represents that it has carefully reviewed this document and hereby agrees that all information herein that is claimed as confidential by the Company (per section 14 of TSCA, 40 CFR Part 720 Subpart E, and 40 CFR Part 2) is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

23 Oct 2015
Date



Maria J. Doa, Ph.D., Director
Chemical Control Division
Office of Pollution Prevention and Toxics

4 Nov 2015
Date

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

“Chemical name” means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the Chemical Abstracts Service’s rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

“Chemical protective clothing” means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

“Company” means the person or persons subject to this Order.

“Commercial use” means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

“Common name” means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

“Consumer” means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

“Consumer product” means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

“Container” means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

“Contract Manufacturer” means a person, outside the Company, who is authorized to manufacture (defined by statute to include import) the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

“Identity” means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

“Immediate use.” A chemical substance is for the “immediate use” of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

“Impervious.” Chemical protective clothing is “impervious” to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

“Manufacturing stream” means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

“MSDS” means material safety data sheet, the written listing of data for the chemical substance.

“NIOSH” means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

“Non-enclosed process” means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

“Non-industrial use” means use other than at a facility where chemical substances or mixtures are manufactured (defined by statute to include import) or processed.

“PMN substance” means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

“Personal protective equipment” means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

“Process stream” means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

“Scientifically invalid” means any significant departure from the EPA-reviewed protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency review that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

“Scientifically equivocal data” means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-reviewed protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

“Sealed container” means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

“Use stream” means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

“Waters of the United States” has the meaning set forth in 40 CFR 122.2.

“Work area” means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

“Workplace” means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B
NOTICE OF TRANSFER
OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

Company (Transferor)

PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice ("PMN") and is governed by a Consent Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(e) of the Toxic Substances Control Act ("TSCA," 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:

___ reasserts,

___ relinquishes, or

___ modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

**NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER**

(continued)

Company (Transferor)

PMN Number

Signature of Authorized Official

Date

Printed Name of Authorized Official

Title of Authorized Official

Successor in Interest

Signature of Authorized Official

Date

Printed Name of Authorized Official

Title of Authorized Official

Address

City, State, Zip Code

**NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER
(continued)**

Successor's Technical Contact

Address

City, State, Zip Code

Phone

**TSCA CONFIDENTIAL
BUSINESS INFORMATION
DOES NOT CONTAIN NATIONAL
SECURITY INFORMATION (E.O. 12065)**